DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
5100 Paint Branch Parkway
College Park, Maryland 20740

May 8, 2003

WARNING LETTER

VIA OVERNIGHT DELIVERY

Dr. Jeffrey Maehr
857 N. Pagosa Blvd., Suite B1
Pagosa Springs, CO 81147

Dear Dr. Maehr:

The Food and Drug Administration (FDA) has reviewed your web site at the following address: www.pure-health-systems.com. This review shows serious violations of the Federal Food, Drug, and Cosmetic Act (the Act) in the labeling of your product Beta Glucan. You can find the Act and implementing regulations through links on FDA's Internet home page at www.fda.gov.

Under the Act, articles intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man are drugs [Section 201(g)(1)(B) of the Act]. Your web site claims that your product is useful in the prevention and treatment of Severe Acute Respiratory Syndrome (SARS) and other diseases. The labeling of your product bears the following claims:

> "Is your immune system prepared for Cancer or Biological Terrorism?" "Recently a new super pneumonia biological threat has arrived, called SARS...." "The solution is to prepare ourselves and our immune systems to be able to fight any such threats." "Beta Glucan has been proven effective even against Anthrax, a deadly biological threat, and against cancer, so imagine what it might do for colds, flu, and other immune system problems?"

These claims cause your product to be a drug, as defined in section 201(g)(1)(B) of the Act. Because the product is not generally recognized as safe and effective when used as labeled, it is also a new drug as defined in section 201(p) of the Act. Under section 505 of the Act, a new drug may not be legally marketed in the United States without an approved New Drug Application (NDA). These drugs are also misbranded within the meaning of section 502(a) of the Act because their labeling is false and misleading in that it suggests that these drugs are

safe and effective for the prevention and treatment of SARS and other diseases, when, in fact, these claims are not supported by reliable scientific evidence. These drugs are also misbranded within the meaning of section 502(f)(1) of the Act, in that the labeling for these drugs fails to bear adequate directions for use.

The above violations are not meant to be an all-inclusive list of deficiencies in your products and their labeling. It is your responsibility to ensure that products marketed by your firm comply with the Act and its implementing regulations.

The Act authorizes the seizure of illegal products and injunctions against manufacturers and distributors of those products. You should take prompt action to correct these deviations and prevent their future recurrence. Failure to do so may result in enforcement action without further notice.

Please advise this office, in writing and within fifteen (15) working days of the receipt of this letter, as to the specific steps you have taken to correct the violations noted above and to assure that similar violations do not occur. If corrective actions cannot be completed within fifteen working days, state the reason for the delay and the time within which the corrections will be completed.

Your reply should be addressed to Compliance Officer Jennifer Thomas at the above address.

Sincerely,

Joseph R. Baca
Director
Office of Compliance
Center for Food Safety and
Applied Nutrition